K 050036

JUN 27 2005

RT300-S Summary of Safety and Effectiveness

(1) Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Andrew Barriskill
Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: 310 691-5467

Prepared on June 24th 2005.

(2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name:

Proprietary name: RT300-S, RT300-SP (FES cycle ergometer)
Common name: Powered Muscle Stimulator
Classification name: Powered Muscle Stimulator

(3) Identification of the legally marketed device to which the submitter claims equivalence:

THERAPEUTIC ALLIANCES, INC. product: "ERGYS", K841112, a class 2 device

(4) A description of the device that is the subject of the premarket notification submission.

The RT300-S is a Functional Electrical Stimulation (FES) cycle ergometer which is composed of:

1 a motorized cycle ergometer (RTI part number SA100047 for adults and SA100044 for children)
2 an FES controller / stimulator (RTI part number SA100090)
3 a stimulation cable which connects the controller / stimulator to cutaneous electrodes (RTI part number SA100091)
4 cutaneous electrodes (12 electrodes for 6 stimulation channels, RTI part number FA100015)

This system allows a person with impaired lower extremity movement to undertake cycle ergometry both actively (utilizing FES evoked lower extremity muscle contractions) and passively (utilizing power developed by the ergometer's motor).

(5) Statement of the intended use of the device:

The RT300-S (adult version) and RT300-SP (pediatric version) are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

The RT300-SP (pediatric version), is intended for population ages 4 to 12 years.

(6) Technological Characteristics

The function of the RT300-S is the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	**RT300-S**	**Predicate**
Power source (energy used)	Mains power	Mains power
Controller	Based on Pocket PC running custom software.	Uses custom controller running custom software.
Stimulator (energy delivered)	0-140mA charge balanced stimulator	0-140mA charge balanced stimulator
Flywheel	Uses motor to create flywheel effect with reduced weight and space.	Uses heavy mechanical flywheel.
Seating	Allows user to remain in their own seating, e.g wheelchair eliminating the need for transfer.	Includes a dedicated seating arrangement.
Passive cycling	Utilizes motor to provide assistance during passive cycling.	Requires manual assistance to provide power during passive cycling.

(b) Performance data

Non clinical testing to determine equivalence has been primarily composed of the following tests:

Test or procedure	**Description**
Review of user documentation for predicate device	Ensure that equivalent functionality is specified and implemented in the new device.
Review of 510(k) submission for	Confirm technical specifications for

predicate device	completion of predicate details in comparison tables
Output characteristic measurement of new device	Confirm technical specifications for completion of new device details in comparison tables
Conduct of system testing	Conduct system testing to verify performance to specification.

Clinical Test	**Description**
Testing with able bodied subjects	The RT300-S was tested on able bodied subjects to confirm correct operation of the system including correct detection of electrode off conditions with varying skin impedances.
Testing with spinal cord injured subjects	The RT300-S is being utilized in clinical studies involving spinal cord injured subjects.

RTI concludes that:

The RT300-S has the same intended use as the predicate device.

The RT300-S has the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness. The safety and effectiveness of using a motor to simulate the predicate device's mechanical flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the motorized ergometer without the stimulation component both in the European Union and in the U.S.A. The safety and effectiveness of the controller has been demonstrated over the development period of the RT300-S.

In conclusion, RTI's clinical and non clinical testing has demonstrated that the RT300-S is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2005

Mr. Andrew Barriskill
Restorative Therapies Incorporated
2263 Boston Street
Baltimore, Maryland 21224

Re: K050036
Trade/Device Name: RT300-S and RT300-SP
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: April 26, 2005
Received: April 26, 2005

Dear Ms. Barriskill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050036

Device Name: RT300-S and RT300-SP

Indications For Use:

The RT300-S (adult version) and RT300-SP (pediatric version) are intended for general rehabilitation for:

a. Relaxation of muscle spasms
b. Prevention or retardation of disuse atrophy
c. Increasing local blood circulation
d. Maintaining or increasing range of motion

The RT300-SP (pediatric version), is intended for population ages 4 to 12 years.

Prescription Use __X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050036